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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,343	04/21/2004	Edward D. Pingleton	A-2926-AV	6799

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APPLIED MEDICAL RESOURCES CORPORATION

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/829,343

Applicant(s)

PINGLETON ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 26, 28, 30 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-25, 27, 29, 31-33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species of the claimed invention: Embodiment I shown in Figures 1 – 4; Embodiment II shown in Figures 6 and 7; Embodiment III shown in Figures 8 and 9; Embodiment IV shown in Figures 10 and 11; Embodiment V shown in Figures 12 and 13 and Embodiment VI shown in Figures 14 – 16.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23 and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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2. During a telephone conversation with Kenneth Vu on 1/5/05 a provisional election was made with traverse to prosecute the invention of Embodiment II. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13, 14, 26, 28, 30 and 34 are withdrawn from further consideration by the examiner, 37 CFR.1.142(b), as being drawn to a non-elected invention. It is noted that Applicant has asserted claims 26 and 30 as being directed to Embodiment II. However, the Examiner believes claims 26 and 30 to be directed to Embodiment V.

### *Claim Objections*

3. Claims 9 and 11 are objected to because of the following informalities: "the first wire" lacks antecedent basis. Appropriate correction is required.

### *Specification*

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because it exceeds 150 words in length.

Correction is required. See MPEP § 608.01(b).

### *Drawings*

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the grinded or tapered tip and the tip spring must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 – 7, 9, 10, 20 – 22, 31, 32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,313,967 to Lieber et al.

In regards to claims 1 – 7, 9, 10, 20 – 22, 31, 32 and 35, Lieber et al. discloses a guidewire (Figures 8) including a wire (130) having a generally rectangular cross-section (Col. 3, lines 35 – 37) having a first and second longitudinal edge, the wire twisting helically around the longitudinal axis of the wire for at least a section of the length of the wire to enhance one of torquability and pushability (Col. 3, lines 40 – 43). The wire is formed of stainless steel or other metallic or polymer alloys (Col. 3, lines 13 – 14). Lieber et al. discloses embodiments where the pitch varies (Figure 8) and where the pitch remains constant (Figure 1). The first and second longitudinal edges vary (132, 134). The wire has a diameter varying from about 0.010" to about 0.060" (Col. 3, line 26). A second wire (116) having a round cross-section helically twists around the first wire. Lieber et al. discloses embodiments having a tapered tip (135) and a tip spring (124).

9. Claims 23 – 25, 27, 29, 31, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,019,736 to Avellanet et al.

In regards to claims 23 – 25, 27, 29, 31, 33 and 35, Avellanet et al. discloses a guidewire (14) including a first wire having a first cross-section and a second wire having a second cross-section, wherein the first and second wires are formed from Nitinol, stainless steel and other metallic alloys (Col. 5, lines 62 – 66) and are helically twisted together around at least a section of the longitudinal axis of the guidewire (Col. 4, lines 64 – 67) to enhance torquability while maintaining flexibility. The first and second cross-sections are generally similar and are a multisided shape (Figure 5).

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10. Claims 1 – 5, 7, 9 – 12, 15 – 18, 22 – 25, 27, 29, 31 – 33 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0151823 to Miyata et al.

In regards to claims 1 – 5, 7, 9 – 12, 15 – 18, 22 – 25, 27, 29, 31 – 33 and 35, Miyata et al. discloses a guidewire including a wire having a generally rectangular cross-section [0115] having a first and second longitudinal edge, the wire twisting helically around the longitudinal axis of the wire for at least a section of the length of the wire [0059] to enhance one of tourqualbility and pushability [0062]. The wire is formed of stainless steel or other metallic or polymer alloys [0017]. Miyata et al. discloses that the pitch can vary remain constant [0116]. The wire has a diameter varying from about 0.010” to about 0.060” [0117]. A second rectangular wire helically twists around the first wire. The first and second wires are held together by the sheer force of being twisted together [0062]. Miyata et al. discloses attaching the wires together by spot gluing or soldering [0089]. Miyata et al. discloses a tip spring (39a) mounted at a distal end of the wire.

### *Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,313,967 to Lieber et al. as applied to claim 1 above.

In regards to claim 8, Lieber et al. fails to disclose the length of the guidewire varying from about 100 cm to 200 cm. However, Lieber et al. discloses that other lengths of the guidewire can be

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made to suit an intended use (Col. 3, lines 24 – 34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the length of the guidewire as disclosed by Lieber et al. from about 100 cm to 200 cm or any length as desired. Furthermore, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0151823 to Miyata et al. as applied to claim 11 above, and further in view of U.S. Patent No. 6,019,736 to Avellanet et al.

In regards to claim 19, Miyata et al. discloses a portion of the guidewire being coated in plastic [0092]. Miyata et al. fails to disclose the guidewire being coextruded with plastic. However, Avellanet et al. discloses coextruding a guidewire with plastic in order to coat the guidewire (Col. 7, lines 63 – 66). It would have been obvious to one having ordinary skill in the art to coat the guidewire and plastic as disclosed by Miyata et al. by extruding the guidewire with the plastic as taught by Avellanet et al. in order to tightly fit the coating over the guidewire (Col. 7, lines 63 – 66).

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,251,085 to Tezuka and U.S. Patent No. 6,770,038 to Balbierz et al. disclose guidewires comprising helically twisted wires.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

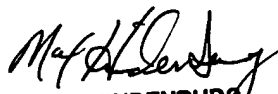


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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